

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION**

WALMART INC.,

Plaintiff,

V.

U.S. DRUG ENFORCEMENT
ADMINISTRATION, *et al.*,

Defendants.

No. 4:20-cv-00817-SDJ

**WALMART'S SUPPLEMENTAL BRIEF IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS**

Pursuant to this Court’s order, Plaintiff Walmart Inc. (“Walmart”) respectfully submits this supplemental brief to address several issues that arose at the oral hearing on Defendants’ motion to dismiss. Defendants argue that “special” rules deny plaintiffs a cause of action against the government, but only the government, for a pre-enforcement challenge. They argue, in effect, that the federal government can, with complete impunity, threaten enforcement actions to coerce massive settlements and coerce private actors to change their conduct, without ever needing to justify government actors’ aggressive theories of liability in a court of law. But Defendants are wrong. Time and again the Supreme Court has made clear that, “where threatened action by *government* is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–29 (2007); *see also Sackett v. EPA*, 566 U.S. 120, 131 (2012) (warning against the government’s “strong-arming ... regulated parties into ‘voluntary compliance’ without the opportunity for judicial review”). The additional authorities discussed during the hearing provide even further support for Walmart’s positions that: (1) the United States has waived its sovereign immunity in

§ 702 of the Administrative Procedure Act (“APA”); (2) a ripe controversy exists between the parties that is justiciable under Article III; and (3) Walmart has a federal cause of action by virtue of the Declaratory Judgment Act (“DJA”) because Defendants could sue Walmart under the Controlled Substances Act (“CSA”).

I. THE UNITED STATES HAS WAIVED ITS SOVEREIGN IMMUNITY.

The United States has waived its sovereign immunity for declaratory challenges to agency action that do not arise under the general provisions of the APA. *See* 5 U.S.C. § 702; *Doe v. United States*, 853 F.3d 792, 798–99 (5th Cir. 2017). This is precisely that kind of challenge.

A. Defendants’ Enforcement Threats Constitute Agency Action.

Defendants have disputed the existence of “agency action” here, but their enforcement threats plainly qualify. “[A]gency action” is defined broadly to include “the whole or [a] part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 489 (5th Cir. 2004) (quoting 5 U.S.C. § 551(13)). A “sanction,” in turn, is any “prohibition, requirement, limitation, or other condition affecting the freedom of a person,” or any “other compulsory or restrictive action.” 5 U.S.C. § 551(10). The Fifth Circuit has been generous in construing this term. In *Doe*, for example, the court held that the government had imposed a “sanction” on the plaintiff by failing to provide a “public forum in which [the plaintiff could seek] to vindicate his rights” and therefore “failed to act and failed to provide relief or a remedy to [the plaintiff].” 853 F.3d at 800.

Defendants’ clear and repeated enforcement threats—set forth in Complaint ¶¶ 18, 57, 115, 119, 129, 133, 135, 142, 145, 155, 174, among others—are a “sanction” for these purposes. By creating a practical dilemma about whether to comply with Defendants’ interpretations of the CSA or risk liability, Defendants’ threats limit and restrict the professional judgment of Walmart’s pharmacists when they dispense controlled substances. The enforcement threats are intended to

force Walmart to comply with the DEA’s overbroad view of the CSA—an action which plainly constitutes a “sanction” by the APA’s text and the Fifth Circuit’s broad interpretation of the term. Indeed, giving regulated entities a way to resolve dilemmas of this sort is a quintessential purpose of the DJA; Defendants’ cramped construction of the § 702 waiver would largely obstruct that important function. All of this is far more concrete “agency action” than was found in *Doe*.

Ciba-Geigy Corp. v. EPA, 801 F.2d 430 (D.C. Cir. 1986), makes clear that enforcement threats are reviewable agency actions. There, the plaintiff sought declaratory and injunctive relief when the EPA “required it to change the labeling of its registered pesticide ... without affording the Company an adjudicatory hearing required by” the substantive statute. *Id.* at 431, 433. The court determined that the complaint alleged agency action ripe for judicial review. *Id.* at 434. Because “[t]he term ‘agency action’ encompasses an agency’s interpretation of law,” it is “the finality of that interpretative position which is relevant for purposes of determining the ripeness of the statutory question”—a requirement courts must apply “in a flexible and pragmatic way.” *Id.* at 435. In *Ciba-Geigy*, the agency had articulated its “interpretation of law” by sending a letter stating that the plaintiff had no statutory right to a hearing and demanding “immediate compliance.” *Id.* at 436–37. The “agency’s pre-litigation position”—and threat of enforcement should the plaintiff fail to comply with it—was thus made clear. *Id.* at 437.

The same is true here. DOJ has articulated its definitive interpretations of the CSA—in repeated communications with Walmart, in the 2007 Rannazzisi letter, in the 2020 Pharmacist Manual, in improperly leaked communications to the media about its investigation of Walmart—and has taken action to enforce those interpretations against other pharmacies and pharmacists, *see United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. Oct. 30, 2020); *United States v. Farmville Disc. Drug, Inc.*, No. 4:20-cv-0018 (E.D.N.C. Jan. 29, 2020); *United States v. Ridley’s*

Fam. Mkts. Inc., No. 1:20-cv-00173 (D. Utah Dec. 4, 2020). Accordingly, Walmart must either comply with Defendants’ overbroad view or risk liability itself. Walmart alleges all of this in its Complaint, which Defendants concede must be taken as true for purposes of this motion, and which is replete with allegations about DOJ’s specific enforcement threats. *See, e.g.*, Compl. ¶¶ 18, 57, 115, 119, 129, 133, 135, 142, 145, 155, 174. *Accord* Amicus Br. of NACDS at 7 (recounting that Defendants “are now threatening civil and criminal liability against pharmacies and pharmacists that do fill facially valid prescriptions” (emphasis omitted)).

Defendants try to distinguish *Ciba-Geigy* by suggesting it extends only to formal, written pronouncements targeting a regulated entity. But the D.C. Circuit nowhere required that a threat of enforcement be *written*, or that the agency have taken any formal step of enforcement. Nor can any such limitation be found in the statutory text. And there is no reason, as a matter of first principles, why the § 702 waiver would turn on the *form* of the enforcement threat. Rather, the D.C. Circuit properly found that “‘agency action’ encompasses an agency’s interpretation of law” and is reviewable where the agency has “definitively stated its position” on a question with both “practical” and “legal” effect on the plaintiff. *Ciba-Geigy*, 801 F.2d at 435, 437. That is true here. In any event, Defendants have made written threats and taken formal enforcement actions, in the form of their lawsuits against other pharmacies. Those suits (along with the subsequently filed enforcement action against Walmart) also rebuff Defendants’ attempt to characterize the agency’s interpretation as “in flux.”

In short, Defendants’ interpretations of the CSA are well-defined and firmly developed. And as in *Ciba-Geigy*, these concrete interpretative positions have “direct and immediate ... effect on the day-to-day business” of Walmart and its pharmacists. *Id.* at 435–36. They amply qualify as “agency action” sufficient to waive sovereign immunity under § 702.

B. Walmart Is Not Launching a Programmatic Challenge.

Defendants’ enforcement threats are both “particular” and “identifiable” within the Fifth Circuit’s “agency action” requirement, so Walmart is not lodging a non-justiciable, blanket challenge to a comprehensive agency program. *Alabama-Coushatta*, 757 F.3d at 489, 491; *Louisiana v. United States*, 948 F.3d 317, 322 (5th Cir. 2020). In the cases discussed at the hearing where the Fifth Circuit found suits amounted to improper programmatic challenges, the government had never threatened the declaratory-judgment plaintiffs with enforcement, so those plaintiffs did not face the coercive dilemma that Defendants have imposed on Walmart. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004); *Alabama-Coushatta*, 757 F.3d at 490; *Louisiana*, 948 F.3d at 321.

Nor would Walmart’s requested relief entangle this Court in the kind of wholesale review that the Fifth Circuit has warned against. Unlike the plaintiffs in each of *Louisiana* and *Alabama-Coushatta*, Walmart challenges concrete positions that Defendants have taken with respect to the meaning of the CSA and its implementing regulations: *viz.*, whether pharmacists are required to document so-called red flags before filling a prescription; whether specific categories of prescriptions are always improper; whether businesses that operate pharmacies carry duties beyond those imposed on their pharmacists (such as aggregating and analyzing data); whether distributors have a duty not to ship suspicious orders until after they have been investigated; and whether civil penalties for allegedly inadequate reporting were available at the time Walmart self-distributed.

Defendants’ positions on these issues are confirmed by their statements to Walmart, *see* Compl. ¶¶ 124, 130, 142, 153, 155; by other statements by Defendants cited in the Complaint, *see, e.g.*, ¶ 51 (Pharmacist Manual); ¶ 149 (DEA letter to distributors); ¶ 63 (DEA letter to National Association of Chain Drug Stores); and by DOJ’s enforcement actions against other regulated parties, *see, e.g.*, ¶ 60. Defendants can hardly deny that its interpretative positions regarding

registrants' duties are fixed. And, as explained above, Defendants may not force regulated parties to conform their conduct to those positions without an opportunity for judicial review. *See Ciba-Giegy*, 801 F.2d at 436.

C. *Danos* Does Not Narrow the Scope of the Waiver Under § 702.

Danos v. Jones, 652 F.3d 577 (5th Cir. 2011), has no effect on this analysis. Danos—a secretary of an impeached and convicted federal judge—sued the Fifth Circuit Judicial Council for suspending the judge's authority to employ staff during the impeachment proceedings. *Id.* at 581. Danos did *not* rely on the § 702 immunity waiver. Instead, she argued that immunity was overcome under *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949), which had held that suits against officers are not suits against the sovereign when the officer's alleged actions are *ultra vires*. *Danos*, 652 F.3d at 582–83.

The Fifth Circuit rejected Danos's *ultra vires* argument for two reasons, neither of which is relevant here. The court held that Danos's claim for injunctive relief was moot because the judge had been removed from office; her damages claim failed because *Larson* does not apply to claims for monetary relief; and she otherwise lacked the necessary injury-in-fact to pursue declaratory relief. *Id.* at 583. This holding is inapplicable here, because the dispute between the parties unquestionably remains live and Walmart does not seek monetary damages.

The court went on to hold that Danos failed to “plead[] a sufficient claim of *ultra vires* action by the Judicial Council” because the Council had at least “a colorable basis” to believe its actions were lawful. *Id.* at 584. But this is simply a gloss on the *Larson* rule; it has no bearing on the scope of § 702, which is a statutory waiver of immunity. Because Danos did not advance an argument based on § 702, the court had no occasion to address the scope of that provision. And nothing in the statute or Fifth Circuit caselaw supports importing the “*ultra vires*” test into § 702. Nor have Defendants argued that they are immune on that basis.

II. A JUSTICIABLE CONTROVERSY EXISTS BETWEEN THE PARTIES.

Parties facing an imminent and credible enforcement threat from the government do not have to expose themselves to liability, or wait until the government exhausts all its enforcement options, before seeking declaratory relief. *See Frozen Food Express v. United States*, 351 U.S. 40, 44 (1956). Rather, a controversy is justiciable if the agency has made its interpretive position clear, including by pursuing similarly-situated regulated entities or simply warning a regulated entity that conduct *may* violate a statute. *N.H. Lottery Comm’n v. Rosen*, No. 19-1835, 2021 WL 191771, at *6 (1st Cir. Jan. 20, 2021). Once the agency has staked out its position, regulated entities need not “run the risk of serious civil and criminal penalties” before seeking clarification on legal issues affecting their day-to-day business. *Ciba-Geigy*, 801 F.2d at 439; *see also Frozen Food*, 351 U.S. at 44 (examining “immediate and practical impact” on regulated entities of agency position that was not “abstract, theoretical, or academic”); *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967). The government cannot avoid review by eschewing formal pronouncements and forcing regulated entities “to sit like Damocles.” *N.H. Lottery Comm’n*, 2021 WL 191771, at *8.

This is especially true with respect to DEA’s positions under the CSA. Two circuits have already squarely rejected the government’s view that a declaratory judgment suit is an improper vehicle for resolving disputes over the meaning of the controlled-substances laws in circumstances less mature than this one. *See N.H. Hemp Council, Inc. v. Marshall*, 203 F.3d 1 (1st Cir. 2000); *Monson v. DEA*, 589 F.3d 952 (8th Cir. 2009). In both cases, plaintiffs who wanted to grow industrial hemp sought judicial review of DEA’s view that the CSA’s definition of “marijuana” could capture that product. And in both cases, the appellate courts concluded that the DJA was a proper vehicle for pre-enforcement resolution of that purely legal dispute.

In *New Hampshire Hemp Council*, the First Circuit reasoned that it had jurisdiction because “[t]he DEA ha[d] made [its view] clear, both by its conduct in New Hampshire and elsewhere.”

203 F.3d at 5. The primary piece of evidence on the DEA’s position was the testimony of one DEA agent in a state legislative debate, but because the government declined to disavow that position, the court saw no issue in adjudicating an “abstract” question “of statutory interpretation.” *Id.* at 3, 5. The Eighth Circuit followed suit in *Monson*, likewise agreeing that the plaintiff could seek a declaratory judgment that the CSA did not apply to their planned activities. 589 F.3d at 955, 958. A justiciable controversy existed because DEA had sent one letter to the State Agricultural Commissioner claiming that the CSA would cover plaintiffs’ activity. *Id.* at 958.

The controversy between the parties here is even more concrete. Rather than relying on a single DEA agent’s testimony or a single letter, Walmart’s complaint details numerous threats by Defendants as well as other statements from the agency setting out its positions. *See supra* Part I. Far from “abstract, theoretical, or academic,” *Frozen Food*, 351 U.S. at 44, the government’s views are finely honed, and they put Walmart under the sword of massive CSA liability (as well as derivatively under the False Claims Act) for its day-to-day dispensing conduct. Resolution of the parties’ legal disputes in this context would be anything but advisory.

III. WALMART HAS A CAUSE OF ACTION.

In their briefs, Defendants argued that while the DJA generally allows a potential defendant to sue by borrowing the federal cause of action that could otherwise be asserted against it, that principle does not apply against the government. Yet, as the hearing confirmed, Defendants cannot cite a single case for that “exception.” The Fifth Circuit has instead made clear that the relevant question is whether the “underlying cause of action”—“*regardless of to whom it belongs*”—is one that “arise[s] under federal law.” *Lowe v. Ingalls Shipbuilding*, 723 F.2d 1173, 1179 (5th Cir. 1984) (emphasis added). Here, there is no dispute that the CSA cause of action is federal; it is irrelevant that the cause of action “belongs” to the government.

Even more important, the hearing exposed that abundant case law refutes the government's suggestion that it is somehow uniquely carved out from the DJA's scope. The First Circuit recently ruled in *New Hampshire Lottery Commission* that the plaintiffs had properly invoked the DJA to challenge the government's interpretation of the Wire Act, 18 U.S.C. § 1084. *See* 2021 WL 191771, at *3, *8. That Act includes no private cause of action, yet neither the government nor the court viewed that as creating any obstacle to review. Rather, the DJA provides a procedure to "enable judicial resolution of a case or controversy that might otherwise be adjudicated at a different time or in a slightly different form." *Id.* at *8.

Nor is there anything unique about the CSA that would lead to a different conclusion. In fact, *New Hampshire Lottery Commission* cited and relied on an earlier First Circuit decision, *New Hampshire Hemp Council*, which held that plaintiffs were entitled to invoke the DJA to secure judicial review of DEA's interpretation of the CSA's definition of marijuana. As explained above, that interpretation generated a credible threat of enforcement of the CSA against the plaintiffs, so there was a justiciable controversy. *See N.H. Hemp Council*, 203 F.3d at 4–5. Again, nobody so much as questioned the availability of the DJA or demanded a private cause of action under the CSA. And the First Circuit is not alone; the Eighth Circuit followed suit in *Monson*, 589 F.3d at 958–60. In short, the authorities discussed at the hearing prove that it is entirely proper to use the DJA to resolve a credible threat of enforcement based on Defendants' interpretation of the CSA.

The same goes for the new argument, raised by Defendants at the hearing, that the APA provides the *exclusive* mechanism for challenging agency action. That is flatly wrong. Nothing in the APA limits the availability of other remedies or causes of action. *See Alabama-Coushatta*, 757 F.3d at 489 (explaining how § 702's immunity waiver "applies when judicial review is sought pursuant to a statutory or non-statutory cause of action that arises completely apart from the general

provisions of the APA.”). No authority restricts a regulated entity to suit under the APA. In fact, the same cases discussed above rebut this argument, too. Most directly, *New Hampshire Lottery Commission* involved “claims under the Declaratory Judgment Act and the APA.” 2021 WL 191771, at *8. Yet the court began with—and resolved the case based exclusively on—the DJA, because it turned out that “the remedy provided by the Declaratory Judgment Act [was] adequate under the circumstances.” *Id.* at *15. Defendants here would turn that framework on its head, *denying* relief under the DJA even if the APA does *not* provide an adequate remedy under the circumstances. *Cf.* 5 U.S.C. § 704 (providing for judicial review of agency action “for which there is no other adequate remedy in a court”).

CONCLUSION

Defendants returned repeatedly during the hearing to the refrain that Walmart should raise its arguments as a defense to the enforcement action pending in the District of Delaware. But Rule 57 makes clear that “[t]he existence of another adequate remedy does not preclude a declaratory judgment that is otherwise appropriate,” Fed. R. Civ. P. 57, and the Supreme Court has underscored that “a federal court’s obligation to hear and decide cases within its jurisdiction is virtually unflagging,” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014) (cleaned up). “Where the legal issue presented is fit for judicial resolution” and “serious penalties” attach to a regulated party’s “noncompliance” with the government’s views, requiring the party to litigate “only as a defense to an action brought by the Government might harm [it] severely and unnecessarily.” *Abbott Labs.*, 387 U.S. at 153. That is the case here. Rule 57 entitles Walmart to a “speedy hearing” to resolve the dilemma in which Walmart and its pharmacists find themselves as a result of the government’s enforcement threats. The Court accordingly should deny Defendants’ motion to dismiss.

Dated: January 29, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 29, 2021, I electronically filed the foregoing motion with the Clerk of the Court using the CM/ECF system.

By: /s/ Clyde Siebman
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